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Merck KGaA, Darmstadt, Germany, to Present 25 Abstracts at ESMO 2026 Highlighting Advances Across Oncology and Rare Tumor Portfolios

- **New data include two-year Phase 3 efficacy and safety update, and quality of life analysis for pimicotinib in tenosynovial giant cell tumor**
- **First presentation of median overall survival results for investigational anti-CEACAM5 ADC precemtabart tocentecan (Precem-TcT) in metastatic colorectal cancer**
- **Scientific program spans tenosynovial giant cell tumor, colorectal cancer, urothelial carcinoma, lung cancer, head & neck cancer, desmoid tumors and emerging oncology pipeline assets**

Not intended for UK-based media

Darmstadt, Germany, October 19, 2026 – Merck KGaA, Darmstadt, Germany, a leading science and technology company, announced that 25 abstracts from its oncology and rare tumor portfolios have been accepted for presentation at the European Society for Medical Oncology (ESMO) Congress 2026, taking place October 23-26 in Madrid, Spain.

The accepted abstracts highlight both established medicines and investigational candidates across multiple tumor types, including tenosynovial giant cell tumor (TGCT), colorectal cancer (CRC), urothelial carcinoma (UC), non-small cell lung cancer (NSCLC), head and neck cancer (SCCHN), desmoid- and other solid-tumors. Presentations include novel treatment approaches, real-world evidence, health-





News Release

related quality-of-life data, long-term follow-up analyses and clinical development updates designed to help address areas of significant unmet medical need.

"Our presence at ESMO 2026 reflects our continued focus on advancing meaningful innovation for people living with cancer and rare tumors," said Victoria Zazulina, M.D., Head of Global Clinical Development, Healthcare business of Merck KGaA, Darmstadt, Germany. "The breadth of data being presented, including potential first-in-class approaches, long-term patient outcomes, quality-of-life analyses and real-world evidence, underscores our commitment to translating scientific innovation into clinically meaningful outcomes for patients."

Key Highlights from Merck KGaA, Darmstadt, Germany's ESMO 2026 Scientific Program

Pimicotinib in Tenosynovial Giant Cell Tumor (TGCT)

Two posters from the pivotal Phase 3 MANEUVER trial will provide additional long-term evidence for pimicotinib in TGCT.

The analyses include:

- A 2-year efficacy and safety update in key symptoms and physical function with extended treatment
- A health-related quality-of-life analysis.

Together, the findings provide new evidence for pimicotinib extending beyond tumor control and include patient-reported data in daily functioning and overall well-being.

Presentations #3747P and #3756P

Monday, October 26, 12:00-12:45 CET.

Precemtabart Tocentecan (Precem-TcT) in Metastatic Colorectal Cancer

Merck KGaA, Darmstadt, Germany will present new and updated results from the Phase 1 PROCEADE®-CRC-01 study evaluating **precemtabart tocentecan (Precem-TcT)**, a potentially first-in-class investigational anti-CEACAM5 antibody-



News Release

drug conjugate (ADC), in patients with heavily pretreated metastatic colorectal cancer (mCRC). The presentation will include:

- The first report of median overall survival (mOS) results for patients treated with Precem-TcT monotherapy at the selected Phase 3 dose of 2.8 mg/kg administered every three weeks
- Updated efficacy and safety data from the Phase 1 PROCEADE-CRC-01 study to support Phase 3 dose selection.

CEACAM5 is a promising target in colorectal cancer, with high overexpression in approximately 90% of tumors, potentially eliminating the need for patient selection. Building on more than 20 years of expertise in colorectal cancer, Merck KGaA, Darmstadt, Germany's Precem-TcT is currently the most advanced anti-CEACAM5 ADC in clinical development, reinforcing the company's commitment to developing differentiated treatment options for patients with advanced disease and limited therapeutic alternatives.

Presentation #824P

Sunday, October 25, 12:00-12:45 CET.

BAVENCIO® (avelumab) in Urothelial Carcinoma

Multiple presentations will expand the evidence base for BAVENCIO in locally advanced or metastatic urothelial carcinoma (la/mUC), including analyses from the JAVELIN Bladder 100 trial and clinical practice.

Highlights include:

- Exploratory analyses from the JAVELIN Bladder 100 trial with avelumab first-line maintenance in locally advanced or metastatic urothelial carcinoma (la/mUC) by NECTIN4 and ERBB2 amplification status
- Three real-world studies describing outcomes with avelumab first-line maintenance in an interim analysis from the AVENUE study, a UK national Cancer Analysis System registry data analysis, and a single-center retrospective observational study from Sweden
- Investigator-sponsored studies including the AVESEC and DISCUS trials evaluating maintenance treatment approaches in the first-line setting.



News Release

**Presentations #4763P, #4758P, #4766TiP, #4782eP, #4796eP, #4850eP
Friday, October 23, 15:15-16:00 CEST.**

TEPMETKO® (tepotinib) in *MET*ex14 Skipping Non-Small Cell Lung Cancer (NSCLC)

New data in *MET* exon 14 (*MET*ex14) skipping NSCLC will further characterize treatment patterns in clinical practice and support the continued development of TPMETKO.

Presentations include:

- A descriptive interim analysis from the MOMENT disease registry showing the most frequently utilized systemic anticancer treatment approaches across lines of therapy
- The study design of COMET, a randomized Phase 3 investigator-sponsored study evaluating tepotinib versus investigator's choice in patients with previously treated *MET*ex14 skipping NSCLC.

Presentation #2701P

Monday, October 26, 12:00-12:45 CET.

OGSIVEO® (nirogacestat) in Desmoid Tumors

A post-hoc analysis from the Phase 3 DeFi trial shows the safety and efficacy of dose reduction in patients receiving OGSIVEO®. This data further builds on the growing body of evidence from the DeFi trial and aims to address the need for evidence on optimized dosing capable of maintain tumor control, and can enable patients to remain on therapy. This post hoc analysis explored the effect of dose reduction on the safety and efficacy of nirogacestat patients with desmoid tumors.

Presentation #3741P

Monday, October 26, 12:00-12:45 CET.

Early-Stage Pipeline Innovation



News Release

Merck KGaA, Darmstadt, Germany will also present the design of the Phase 1 TITER study evaluating **M0324**, a novel MUC1-conditional CD40 agonist, in selected advanced solid tumors. An immuno-oncology approach, M0324 is engineered to selectively activate CD40-expressing immune cells in the presence of MUC-1-overexpressing tumor cells.

Poster #1144eTiP

Developmental Therapeutics e-Poster Session.

Additional Company-Sponsored Activities at ESMO 2026

Two Medical Symposia:

- **'Striving for more: the cutting edge of therapeutic developments in mCRC'**

Saturday, October 24, 1:00-2:30 CEST, Leon Auditorium, Hall 4, IFEMA, Madrid
Chaired by Dr. Fortunato Ciardiello, an expert faculty will cover key topics including personalized treatment in RASwt/BRAFwt mCRC, innovative data in BRAFmt mCRC, advances in later line treatment and emerging data for ADCs in mCRC.

- **'Care for Rare: desmoid tumors in clinical practice'**

Monday, October 26, 1:00-2:30PM CET, Santander Auditorium, Hall 10, IFEMA, Madrid

An expert faculty, co-chaired by Dr. Ana Sebio Garcia (Spain), and Dr. Bernd Kasper (Germany) will discuss desmoid tumor management, evolving guidelines and therapies, and real-world treatment challenges. A patient advocate will also share their lived experience with a desmoid tumor.

Advancing Science Across Oncology and Rare Tumors

The breadth of data being presented at ESMO 2026 reflects Merck KGaA, Darmstadt, Germany's continued commitment to advancing scientific innovation across oncology and rare tumors. The company's presentations span early- and late-stage clinical development, real-world evidence, translational research, quality-of-life analyses and patient-centered outcomes.



News Release

Together, the 25 accepted abstracts highlight Merck KGaA, Darmstadt, Germany's efforts to help address unmet needs across a broad spectrum of cancers through differentiated therapeutic approaches, established medicines and a pipeline designed to help make a meaningful impact for patients living with cancer and rare tumors.

For more information on Merck KGaA, Darmstadt, Germany's presentations at the ESMO Congress 2026, please visit the [ESMO 2026 Conference Calendar](#).

Select Merck KGaA, Darmstadt, Germany-related abstracts accepted for the ESMO Congress 2026 include:

**All presentations will be in the Poster Area, Hall 5*

Tumor Type	Title	Speaker	Poster #	Session Date & Time
Pimicotinib				
TGCT	Pimicotinib in patients with tenosynovial giant cell tumour (TGCT): 2-year analysis of the phase 3 MANEUVER trial	Gelderblom, H	3747P	Mon, Oct 26 12:00–12:45 PM CET
TGCT	The impact of pimicotinib on quality of life (QoL) in patients with tenosynovial giant cell tumour (TGCT): EQ-5D-5L findings from the phase 3 MANEUVER trial	Razak, ARA	3756P	Mon, Oct 26 12:00–12:45 PM CET
Precemtabart tocentecan				
mCRC	Precemtabart tocentecan (Precem-TcT) in patients with metastatic colorectal cancer (mCRC): Updated survival data from the Phase 1 PROCEADE®-CRC-01 study	Garcia-Carbonero, R	824P	Sun, Oct 25 12:00–12:45 PM CET
BAVENCIO® (avelumab)				
UC	Outcomes with first-line (1L) platinum-based chemotherapy (PBC) and avelumab 1L maintenance in locally advanced or metastatic urothelial carcinoma (la/mUC) by NECTIN4 and ERBB2 amplification status: exploratory analyses from JAVELIN Bladder 100	Klümper, N	4763P	Fri, Oct 23 3:15–4:00 PM CEST
UC	Avelumab first-line maintenance (1LM) for locally advanced or metastatic urothelial carcinoma (la/mUC) in Europe and Russia: interim overall population and Spain subgroup analyses from the real-world AVENUE study	Diaz, AM	4782eP	Fri, Oct 23 3:15–4:00 PM CEST
UC	Predictors of systemic anticancer therapy (SACT) receipt and survival outcomes in adults with locally advanced or metastatic urothelial carcinoma (la/mUC) in England	Stevenson, R	4796eP	Fri, Oct 23 3:15–4:00 PM CEST
UC	Treatment (tx) rates and predictors of overall survival (OS) among patients	Aly, M	4850eP	Fri, Oct 23 3:15–4:00 PM CEST



News Release

	(pts) with locally advanced or metastatic urothelial carcinoma (la/mUC): findings from a retrospective observational study in Sweden			
UC	Outcomes of patients who successfully switched from chemotherapy to avelumab in the randomised DISCUS trial	Membribes Coco, S	4758P	Fri, Oct 23 3:15–4:00 PM CEST
UC	Maintenance AVElumab after SECond line platinum-based chemotherapy for metastatic urothelial urothelialcarcinoma: AVESEC trial – GOIRC-02-2025	Mollica, V	4766TiP	Fri, Oct 23 3:15–4:00 PM CEST
OGSIVEO® (nirogacestat)				
Desmoid	Effect of dose reduction on the safety and efficacy of nirogacestat in patients with desmoid tumors: post hoc analyses of the DeFi trial	Vincenzi, B	3741P	Mon, Oct 26 12:00–12:45 PM CET
M0324				
Developmental	TITER, a phase 1 study of M0324, a novel MUC-1-conditional CD40 agonist, in patients with selected advanced solid tumors	Marron, T	1144eTiP	e-Poster, Developmental Therapeutics, Hall 5

About pimicotinib (ABSK021)

Pimicotinib, developed by Abbisko Therapeutics, is a novel, orally administered, selective and potent small-molecule inhibitor of CSF-1R. Pimicotinib has been approved for the treatment of adult patients with symptomatic TGCT for which surgical resection will potentially cause functional limitation or relatively severe morbidity by China National Medical Products Administration (NMPA) and Health Canada. Pimicotinib has received priority medicine (PRIME) designation from the European Medicines Agency (EMA). Merck KGaA, Darmstadt, Germany, holds worldwide commercialization rights for pimicotinib.

About Precentabart tocentecan

Precentabart tocentecan is an investigational anti-CEACAM5 antibody-drug conjugate (ADC). Leveraging the company's novel linker-payload technology, precentabart tocentecan is the first CEACAM5 ADC with an exatecan payload, a potent topoisomerase inhibitor (TOP1i), which has been rationally designed for stability in circulation and superior cancer cell killing activity. Beyond the direct effect on the target cell, precentabart tocentecan has been shown in preclinical research to induce tumor cell death through a bystander effect in which exatecan permeates the cell membrane to neighboring cells, inducing apoptosis (cell death). This bystander effect within the tumor



News Release

microenvironment may enhance efficacy. Precentabart tocentecan is currently being evaluated across tumor types with CEACAM5 expression and a high unmet need, including metastatic colorectal cancer (mCRC), gastric cancer (GC), non-small cell lung cancer (NSCLC), and pancreatic ductal adenocarcinoma (PDAC).

About BAVENCIO® (avelumab)

BAVENCIO is a human anti-programmed death ligand-1 (PD-L1) antibody. BAVENCIO has been shown in preclinical models to engage both the adaptive and innate immune functions. By blocking the interaction of PD-L1 with PD-1 receptors, BAVENCIO has been shown to release the suppression of the T cell-mediated antitumor immune response in preclinical models.

BAVENCIO Approved Indications

BAVENCIO® (avelumab) is indicated in the US for the maintenance treatment of patients with locally advanced or metastatic urothelial carcinoma (UC) that has not progressed with first-line platinum-containing chemotherapy. BAVENCIO is also indicated for the treatment of patients with locally advanced or metastatic UC who have disease progression during or following platinum-containing chemotherapy, or have disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy.

BAVENCIO in combination with axitinib is indicated in the US for the first-line treatment of patients with advanced renal cell carcinoma (RCC).

In the US, BAVENCIO is indicated for the treatment of adults and pediatric patients 12 years and older with metastatic Merkel cell carcinoma (MCC).

BAVENCIO is currently approved for at least one indication for patients in more than 50 countries.

BAVENCIO Important Safety Information from the US FDA-Approved Label

BAVENCIO can cause **severe and fatal immune-mediated adverse reactions** in any organ system or tissue and at any time after starting treatment with a PD-1/PD-L1 blocking antibody, including after discontinuation of treatment.



News Release

Early identification and management of immune-mediated adverse reactions are essential

to ensure safe use of PD-1/PD-L1 blocking antibodies. Monitor patients closely for symptoms and signs that may be clinical manifestations of underlying immune-mediated adverse reactions. Evaluate liver enzymes, creatinine, and thyroid function at baseline and periodically during treatment. In cases of suspected immune-mediated adverse reactions, initiate appropriate work-up to exclude alternative etiologies, including infection. Institute medical management promptly, including specialty consultation as appropriate.

No dose reduction for BAVENCIO is recommended. For immune-mediated adverse reactions, withhold or permanently discontinue BAVENCIO depending on severity.

In general, withhold BAVENCIO for severe (Grade 3) immune-mediated adverse reactions. Permanently discontinue BAVENCIO for life-threatening (Grade 4) immune-mediated adverse reactions, recurrent severe (Grade 3) immune-mediated reactions that require systemic immunosuppressive treatment, or an inability to reduce corticosteroid dose to 10 mg or less of prednisone or equivalent per day within 12 weeks of initiating corticosteroids. In general, if BAVENCIO requires interruption or discontinuation, administer systemic corticosteroid therapy (1 to 2 mg/kg/day prednisone or equivalent) until improvement to Grade 1 or less. Upon improvement to Grade 1 or less, initiate corticosteroid taper and continue to taper over at least 1 month. Consider administration of other systemic immunosuppressants in patients whose immune-mediated adverse reactions are not controlled with corticosteroid therapy. Toxicity management guidelines for adverse reactions that do not necessarily require systemic corticosteroids (eg, endocrinopathies and dermatologic reactions) are discussed in subsequent sections.

BAVENCIO can cause **immune-mediated pneumonitis**. Withhold BAVENCIO for Grade 2 and permanently discontinue for Grade 3 or Grade 4 pneumonitis. Immune-mediated pneumonitis occurred in 1.1% (21/1854) of patients, including fatal (0.1%), Grade 4 (0.1%), Grade 3 (0.3%), and Grade 2 (0.6%) adverse reactions. Systemic corticosteroids were required in all (21/21) patients with pneumonitis.



News Release

BAVENCIO can cause **immune-mediated colitis**. The primary component of immune-mediated colitis consisted of diarrhea. Cytomegalovirus infection/reactivation has been reported in patients with corticosteroid-refractory immune-mediated colitis. In cases of corticosteroid-refractory colitis, consider repeating infectious workup to exclude alternative etiologies. Withhold BAVENCIO for Grade 2 or Grade 3, and permanently discontinue for Grade 4 colitis. Immune-mediated colitis occurred in 1.5% (27/1854) of patients, including Grade 3 (0.4%) and Grade 2 (0.8%) adverse reactions. Systemic corticosteroids were required in all (27/27) patients with colitis.

BAVENCIO can cause **hepatotoxicity and immune-mediated hepatitis**. Withhold or permanently discontinue BAVENCIO based on tumor involvement of the liver and severity of aspartate aminotransferase (AST), alanine aminotransferase (ALT), or total bilirubin elevation. Immune-mediated hepatitis occurred with BAVENCIO as a single agent in 1.1% (20/1854) of patients, including fatal (0.1%), Grade 3 (0.8%), and Grade 2 (0.2%) adverse reactions. Systemic corticosteroids were required in all (20/20) patients with hepatitis.

BAVENCIO in combination with axitinib can cause hepatotoxicity with higher-than-expected frequencies of Grade 3 and 4 ALT and AST elevation compared to BAVENCIO alone. Consider more frequent monitoring of liver enzymes as compared to when the drugs are used as monotherapy. For elevated liver enzymes, interrupt BAVENCIO and axitinib and consider administering corticosteroids as needed.

BAVENCIO can cause primary or secondary **immune-mediated adrenal insufficiency**. For Grade 2 or higher adrenal insufficiency, initiate symptomatic treatment, including hormone replacement, as clinically indicated. Withhold BAVENCIO for Grade 3 or Grade 4 endocrinopathies until clinically stable or permanently discontinue depending on severity. Immune-mediated adrenal insufficiency occurred in 0.6% (11/1854) of patients, including Grade 3 (0.1%) and Grade 2 (0.4%) adverse reactions. Systemic corticosteroids were required in all (11/11) patients with adrenal insufficiency.

BAVENCIO can cause **immune-mediated hypophysitis**. Hypophysitis can present with acute symptoms associated with mass effect such as headache, photophobia,



News Release

or visual field defects. Hypophysitis can cause hypopituitarism. Initiate hormone replacement, as clinically indicated. Withhold BAVENCIO for Grade 3 or Grade 4 endocrinopathies until clinically stable or permanently discontinue depending on severity. Immune-mediated pituitary disorders occurred in 0.1% (1/1854) of patients, which was a Grade 2 (0.1%) adverse reaction.

BAVENCIO can cause **immune-mediated thyroid disorders**. Thyroiditis can present with or without endocrinopathy. Hypothyroidism can follow hyperthyroidism. Initiate hormone replacement for hypothyroidism or institute medical management of hyperthyroidism, as clinically indicated. Withhold BAVENCIO for Grade 3 or Grade 4 endocrinopathies until clinically stable or permanently discontinue depending on severity. Thyroiditis occurred in 0.2% (4/1854) of patients, including Grade 2 (0.1%) adverse reactions. Hyperthyroidism occurred in 0.4% (8/1854) of patients, including Grade 2 (0.3%) adverse reactions. Systemic corticosteroids were required in 25% (2/8) of patients with hyperthyroidism. Hypothyroidism occurred in 5% (97/1854) of patients, including Grade 3 (0.2%) and Grade 2 (3.6%) adverse reactions. Systemic corticosteroids were required in 6% (6/97) of patients with hypothyroidism.

BAVENCIO can cause **immune-mediated type I diabetes mellitus**, which can present with diabetic ketoacidosis. Monitor patients for hyperglycemia or other signs and symptoms of diabetes. Initiate treatment with insulin as clinically indicated. Withhold BAVENCIO for Grade 3 or Grade 4 endocrinopathies until clinically stable or permanently discontinue depending on severity. Immune-mediated type I diabetes mellitus occurred in 0.2% (3/1854) of patients, including Grade 3 (0.2%) adverse reactions.

BAVENCIO can cause **immune-mediated nephritis with renal dysfunction**. Withhold BAVENCIO for Grade 2 or Grade 3, and permanently discontinue for Grade 4 increased blood creatinine. Immune-mediated nephritis with renal dysfunction occurred in 0.1% (2/1854) of patients, including Grade 3 (0.1%) and Grade 2 (0.1%) adverse reactions. Systemic corticosteroids were required in all (2/2) patients with nephritis with renal dysfunction.



News Release

BAVENCIO can cause **immune-mediated dermatologic adverse reactions**, including rash or dermatitis. Exfoliative dermatitis including Stevens Johnson Syndrome (SJS), drug rash with eosinophilia and systemic symptoms (DRESS), and toxic epidermal necrolysis (TEN), has occurred with PD-1/PD-L1 blocking antibodies. Topical emollients and/or topical corticosteroids may be adequate to treat mild to moderate non-exfoliative rashes. Withhold BAVENCIO for suspected and permanently discontinue for confirmed SJS, TEN, or DRESS. Immune-mediated dermatologic adverse reactions occurred in 6% (108/1854) of patients, including Grade 3 (0.1%) and Grade 2 (1.9%) adverse reactions. Systemic corticosteroids were required in 25% (27/108) of patients with dermatologic adverse reactions.

BAVENCIO can result in **other immune-mediated adverse reactions**. Other clinically significant immune-mediated adverse reactions occurred at an incidence of <1% in patients who received BAVENCIO or were reported with the use of other PD-1/PD-L1 blocking antibodies. For **myocarditis**, permanently discontinue BAVENCIO for Grade 2, Grade 3, or Grade 4. For **neurological toxicities**, withhold BAVENCIO for Grade 2 and permanently discontinue for Grade 3 or Grade 4.

BAVENCIO can cause severe or life-threatening **infusion-related reactions**. Premedicate patients with an antihistamine and acetaminophen prior to the first 4 infusions and for subsequent infusions based upon clinical judgment and presence/severity of prior infusion reactions. Monitor patients for signs and symptoms of infusion-related reactions, including pyrexia, chills, flushing, hypotension, dyspnea, wheezing, back pain, abdominal pain, and urticaria. Interrupt or slow the rate of infusion for Grade 1 or Grade 2 infusion-related reactions. Permanently discontinue BAVENCIO for Grade 3 or Grade 4 infusion-related reactions. Infusion-related reactions occurred in 26% of patients, including three (0.2%) Grade 4 and ten (0.5%) Grade 3 infusion-related reactions. Eleven (85%) of the 13 patients with Grade ≥ 3 reactions were treated with intravenous corticosteroids.

Fatal and other serious **complications of allogeneic hematopoietic stem cell transplantation (HSCT)** can occur in patients who receive HSCT before or after being treated with a PD-1/PD-L1 blocking antibody. Follow patients closely for



News Release

evidence of transplant-related complications and intervene promptly. Consider the benefit versus risks of treatment with a PD-1/PD-L1 blocking antibody prior to or after an allogeneic HSCT.

BAVENCIO in combination with axitinib can cause **severe and fatal cardiovascular events**. Consider baseline and periodic evaluations of left ventricular ejection fraction. Monitor for signs and symptoms of cardiovascular events. Optimize management of cardiovascular risk factors, such as hypertension, diabetes, or dyslipidemia. Discontinue BAVENCIO and axitinib for Grade 3-4 cardiovascular events.

BAVENCIO can cause **fetal harm** when administered to a pregnant woman. Advise patients of the potential risk to a fetus including the risk of fetal death. Advise females of childbearing potential to use effective contraception during treatment with BAVENCIO and for at least 1 month after the last dose of BAVENCIO. It is not known whether BAVENCIO is excreted in human milk. Advise a lactating woman **not to breastfeed** during treatment and for at least 1 month after the last dose of BAVENCIO due to the potential for serious adverse reactions in breastfed infants.

The most common adverse reactions (all grades, $\geq 20\%$) in patients with **metastatic Merkel cell carcinoma (MCC)** were fatigue (47%), musculoskeletal pain (29%), infusion-related reaction (26%), rash (25%), nausea (23%), constipation (22%), cough (22%), and diarrhea (21%).

Laboratory abnormalities worsening from baseline (all grades, $\geq 20\%$) in patients with **metastatic MCC** were decreased lymphocyte count (51%), decreased hemoglobin (40%), increased aspartate aminotransferase (31%), decreased platelet count (23%), increased alanine aminotransferase (22%), and increased lipase (21%).

A **fatal adverse reaction** (sepsis) occurred in one (0.3%) patient with **locally advanced or metastatic urothelial carcinoma (UC)** receiving BAVENCIO + best supportive care (BSC) as first-line maintenance treatment. In patients with previously treated locally advanced or metastatic UC, fourteen patients (6%) who



News Release

were treated with BAVENCIO experienced either pneumonitis, respiratory failure, sepsis/urosepsis, cerebrovascular accident, or gastrointestinal adverse events, which led to death.

The most common adverse reactions (all grades, $\geq 20\%$) in patients with **locally advanced or metastatic UC** receiving BAVENCIO + BSC (vs BSC alone) as first-line maintenance treatment were fatigue (35% vs 13%), musculoskeletal pain (24% vs 15%), urinary tract infection (20% vs 11%), and rash (20% vs 2.3%). In patients with previously treated locally advanced or metastatic UC receiving BAVENCIO, the most common adverse reactions (all grades, $\geq 20\%$) were fatigue, infusion-related reaction, musculoskeletal pain, nausea, decreased appetite, and urinary tract infection.

The most common adverse reactions (all grades, $\geq 20\%$) **in patients with RCC** (with axitinib) were diarrhea, fatigue, hypertension, musculoskeletal pain, nausea, mucositis, palmar-plantar erythrodysesthesia, dysphonia, decreased appetite, hypothyroidism, rash, hepatotoxicity, cough, dyspnea, abdominal pain, and headache.

Selected laboratory abnormalities worsening from baseline (all grades, $\geq 20\%$) in patients with **locally advanced or metastatic UC** receiving BAVENCIO + BSC (vs BSC alone) as first-line maintenance treatment were blood triglycerides increased (34% vs 28%), alkaline phosphatase increased (30% vs 20%), blood sodium decreased (28% vs 20%), lipase increased (25% vs 16%), aspartate aminotransferase (AST) increased (24% vs 12%), blood potassium increased (24% vs 16%), alanine aminotransferase (ALT) increased (24% vs 12%), blood cholesterol increased (22% vs 16%), serum amylase increased (21% vs 12%), hemoglobin decreased (28% vs 18%), and white blood cell decreased (20% vs 10%).

Please see full [Prescribing Information](#) and [Medication Guide](#).

ABOUT TEPMETKO® (tepotinib)

TEPMETKO is a once-daily oral MET inhibitor that inhibits the oncogenic MET receptor signaling caused by *MET* (gene) alterations. Discovered and developed in-house at



News Release

Merck KGaA, Darmstadt, Germany, TEPMETKO has a highly selective mechanism of action, with the potential to improve outcomes in aggressive tumors that have a poor prognosis and harbor these specific alterations.

TEPMETKO is the first oral MET inhibitor to have received a regulatory approval anywhere in the world for the treatment of advanced non-small cell lung cancer (NSCLC) harboring *MET* gene alterations, with its approval in Japan in March 2020. In February 2022, the European Commission (EC) approved once-daily oral TEPMETKO as monotherapy for the treatment of adult patients with advanced NSCLC harboring alterations leading to mesenchymal-epithelial transition factor gene exon 14 (*MET*ex14) skipping, who require systemic therapy following prior treatment with immunotherapy and/or platinum-based chemotherapy. In February 2024, the US Food and Drug Administration granted full approval for TEPMETKO. The conversion from accelerated approval, which the company received in February 2021, to full FDA approval is based on additional data from the ongoing Phase II VISION study, the largest trial of its kind. The updated label includes revised data for overall response rate and duration of response, as well as safety outcomes for more than 300 patients who were treated with TEPMETKO once-daily for metastatic NSCLC with *MET*ex14 skipping alterations.

TEPMETKO has been granted market authorization, and is available in more than 50 markets globally. Submissions and reviews of medical authorities applications to other regions are ongoing.

TEPMETKO Approved Indications

TEPMETKO is indicated for the treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) harboring mesenchymal-epithelial transition (*MET*) exon 14 skipping alterations.

TEPMETKO Important Safety Information From the FDA Approved Label

TEPMETKO can cause **interstitial lung disease (ILD)/pneumonitis**, which can be fatal. Monitor patients for new or worsening pulmonary symptoms indicative of ILD/pneumonitis (eg, dyspnea, cough, fever). Immediately withhold TEPMETKO in patients with suspected ILD/pneumonitis and permanently discontinue if no other potential causes of ILD/pneumonitis are identified. ILD/pneumonitis occurred in 2%



News Release

of patients treated with TEPMETKO, with one patient experiencing a Grade 3 or higher event; this event resulted in death.

TEPMETKO can cause **hepatotoxicity**, which can be fatal. Monitor liver function tests (including alanine aminotransferase [ALT], aspartate aminotransferase [AST], and total bilirubin) prior to the start of TEPMETKO, every 2 weeks during the first 3 months of treatment, then once a month or as clinically indicated, with more frequent testing in patients who develop increased transaminases or total bilirubin. Based on the severity of the adverse reaction, withhold, dose reduce, or permanently discontinue TEPMETKO. Increased ALT/increased AST occurred in 18% of patients treated with TEPMETKO. Grade 3 or 4 increased ALT/AST occurred in 4.7% of patients. A fatal adverse reaction of hepatic failure occurred in one patient (0.2%). The median time-to-onset of Grade 3 or higher increased ALT/AST was 47 days (range 1 to 262).

TEPMETKO can cause **pancreatic toxicity** in the form of elevations in amylase and lipase levels. Increased amylase and/or lipase occurred in 13% of patients, with Grade 3 and 4 increases occurring in 5% and 1.2% of patients, respectively. Monitor amylase and lipase levels at baseline and regularly during treatment with TEPMETKO and temporarily withhold, dose reduce, or permanently discontinue based on severity of the adverse event.

TEPMETKO can cause **embryo-fetal toxicity**. Based on findings in animal studies and its mechanism of action, TEPMETKO can cause fetal harm when administered to a pregnant woman. Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential or males with female partners of reproductive potential to use effective contraception during treatment with TEPMETKO and for one week after the last dose.

Avoid concomitant use of TEPMETKO with certain **P-gp substrates** where minimal concentration changes may lead to serious or life-threatening toxicities. If concomitant use is unavoidable, reduce the P-gp substrate dosage if recommended in its approved product labeling.

Fatal adverse reactions occurred in one patient (0.3%) due to pneumonitis, one patient (0.3%) due to hepatic failure, one patient (0.3%) due to dyspnea from fluid overload, one patient (0.3%) due to pneumonia, one patient (0.3%) due to sepsis, and one patient (0.3%) from unknown cause.



News Release

Serious adverse reactions occurred in 51% of patients who received TEPMETKO. Serious adverse reactions in >2% of patients included pleural effusion (6%), pneumonia (6%), edema (5%), general health deterioration (3.8%), dyspnea (3.5%), musculoskeletal pain (2.9%), and pulmonary embolism (2.2%).

The most common adverse reactions ($\geq 20\%$) in patients who received TEPMETKO were edema (81%), nausea (31%), fatigue (30%), musculoskeletal pain (30%), diarrhea (29%), dyspnea (24%), rash (21%), and decreased appetite (21%).

Clinically relevant adverse reactions in <10% of patients who received TEPMETKO included ILD/pneumonitis, fever, dizziness, pruritus, and headache.

Selected laboratory abnormalities ($\geq 20\%$) from baseline in patients receiving TEPMETKO in descending order were: decreased albumin (81%), increased creatinine (60%), decreased lymphocytes (57%), increased alkaline phosphatase (ALP) (52%), increased ALT (50%), increased AST (40%), decreased sodium (36%), decreased hemoglobin (31%), increased gamma-glutamyltransferase (GGT) (29%), increased potassium (26%), increased amylase (25%), decreased leukocytes (25%), decreased platelets (24%), and increased lipase (21%).

The most common Grade 3-4 laboratory abnormalities ($\geq 2\%$) in descending order were: decreased lymphocytes (15%), decreased albumin (9%), decreased sodium (9%), increased GGT (6%), increased amylase (5%), increased lipase (5%), increased ALT (4.9%), increased AST (3.6%), and decreased hemoglobin (3.6%).

Prescribing Information for TEPMETKO.

ABOUT OGSIVEO® (nirogacestat)

OGSIVEO, for adults with progressing desmoid tumors who require systemic treatment—a rare, locally aggressive type of soft tissue tumor that can cause severe pain—it is the first and only therapy of its kind to be approved by the US Food and Drug Administration (FDA), European Medicines Agency (EMA) and the UK Medicines and Healthcare products Regulatory Agency (MHRA). OGSIVEO is the most prescribed systemic therapy in the United States for this indication.

Approved Indications



News Release

OGSIVEO is indicated in the US and EU for adult patients with progressing desmoid tumors who require systemic treatment

Important Safety Information from the FDA Approved Label

This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions.

OGSIVEO can cause **diarrhea**, which can sometimes be severe. Diarrhea occurred in 84% of patients treated with OGSIVEO, and included Grade 3 events in 16% of patients. Median time to first diarrhea event was 9 days (range: 2 to 434 days). Monitor patients and manage using antidiarrheal medications. Modify dose as recommended.

OGSIVEO can cause **ovarian toxicity** which can impair female reproductive function and fertility. Impact on fertility may depend on factors like duration of therapy and state of gonadal function at time of treatment. Long-term effects of OGSIVEO on fertility have not been established. Advise patients on the potential risks for ovarian toxicity before initiating treatment. Monitor patients for changes in menstrual cycle regularity or the development of symptoms of estrogen deficiency, including hot flashes, night sweats, and vaginal dryness.

OGSIVEO can cause **hepatotoxicity** with ALT or AST elevations occurring in 30% and 33% of patients treated with OGSIVEO, respectively. Grade 3 ALT or AST elevations ($>5 \times \text{ULN}$) occurred in 6% and 2.9% of patients. Monitor liver function tests regularly and modify dose as needed.

OGSIVEO can cause **non-melanoma skin cancers**. New cutaneous squamous cell carcinoma and basal cell carcinoma occurred in 2.9% and 1.4% of patients treated with OGSIVEO, respectively. Perform dermatologic evaluations prior to initiation of OGSIVEO and routinely during treatment.

OGSIVEO can cause **electrolyte abnormalities**. Decreased phosphate (65%) and potassium (22%) occurred in OGSIVEO-treated patients. Phosphate $<2 \text{ mg/dL}$ occurred in 20% of patients. Grade 3 decreased potassium occurred in 1.4% of patients. Monitor phosphate and potassium levels regularly and supplement as necessary. Modify dose as recommended.



News Release

OGSIVEO can cause **hypersensitivity reactions**, including severe hypersensitivity reactions, have been reported with postmarketing use of OGSIVEO. Monitor patients for signs and symptoms of hypersensitivity during treatment with OGSIVEO and manage as clinically indicated. Interrupt dosing or permanently discontinue OGSIVEO depending on the severity.

OGSIVEO can cause **embryo-fetal toxicity**. Based on findings in animal studies, OGSIVEO can cause fetal harm when administered to pregnant women. Advise pregnant women of the potential risk to a fetus. Advise females and males of reproductive potential to use effective contraception during treatment with OGSIVEO and for 1 week after the last dose.

The most common adverse reactions ($\geq 15\%$) were diarrhea (84%), ovarian toxicity (75% in the 36 females of reproductive potential), rash (68%), nausea (54%), fatigue (54%), stomatitis (39%), headache (30%), abdominal pain (22%), cough (20%), alopecia (19%), upper respiratory tract infection (17%), and dyspnea (16%).

Serious adverse reactions occurred in 20% of patients who received OGSIVEO. Serious adverse reactions occurring in $\geq 2\%$ of patients were ovarian toxicity (4%).

The most common laboratory abnormalities ($\geq 15\%$) were decreased phosphate, increased urine glucose, increased urine protein, increased AST, increased ALT, and decreased potassium.

Full [Prescribing Information](#) for OGSIVEO.

About SpringWorks Therapeutics

SpringWorks Therapeutics, a healthcare company of Merck KGaA, Darmstadt, Germany, is a commercial-stage biopharmaceutical company dedicated to improving the lives of patients with rare tumors. We developed and are commercializing the first FDA and EC approved medicine for adults with desmoid tumors and the first FDA and EC approved medicine for both adults and children with neurofibromatosis type 1 associated plexiform neurofibromas (NF1-PN).

About Merck KGaA, Darmstadt, Germany

Merck KGaA, Darmstadt, Germany, a leading science and technology company, operates across life science, healthcare and electronics. More than 62,000 employees work to make a positive difference to millions of people's lives every day by creating more joyful and sustainable ways to live. From providing products and services that accelerate drug development and manufacturing as well as discovering unique ways to treat the most challenging diseases to enabling the intelligence of devices – the company is everywhere. In 2025, Merck KGaA, Darmstadt, Germany, generated sales of € 21.1 billion in 65 countries.

The company holds the global rights to the name and trademark "Merck" internationally. The only exceptions are the United States and Canada, where the business sectors of Merck KGaA, Darmstadt, Germany, operate as MilliporeSigma in life science, EMD Serono in healthcare and EMD Electronics in electronics. Since its founding in 1668, scientific exploration and responsible entrepreneurship have been key to the company's technological and scientific advances. To this day, the founding family remains the majority owner of the publicly listed company.



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